7. SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Premarket Notification 510(k) Number: K000132

Date of Summary Preparation: January 5, 2000

Distributor:
Pharmacia & Upjohn
Diagnostics Division, US Operation
7425-248-1
7000 Portage Road
Kalamazoo, MI 49001

Manufacturer:
Pharmacia & Upjohn, Diagnostics AB
S-751 82 Uppsala, Sweden
and
MIAB
Dragarbrunnsgatan 65
S-75320 Uppsala

Company Contact Person:
Karen E. Matis
Manager, Regulatory Affairs and Quality Management
Pharmacia & Upjohn
Diagnostics Division, US Operation
7000 Portage Road
7425-248-01
Kalamazoo, MI 49001
(614) 794-3324 (Phone)
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Device Name: Allergen ImmunoCAP™- c74, e89, ex2 , ex70, ex71, ex73, fx8, fx9, fx10, fx16, fx73, i72, i75, i76, k71, k73, k81, k87, m80, m81, mx2 , mx3, pax1, pax3, pax5, tx5 , tx8, wx5, wx6, wx7

Allergen ImmunoCAP™ c74-wx7
510(k) Submission
Section 7. Summary of Safety and Effectiveness

Common Name: Solid phase components of immunological test system to measure allergen specific IgE antibodies.

Classification:

Product Name	Product Code	Class	CFR
Allergen ImmunoCAP™ c74, e89, ex2 , ex70, ex71, ex73, fx8, fx9, fx10, fx16, fx73, i72, i75, i76, k71, k73, k81, k87, m80, m81, mx2 , mx3, pax1, pax3, pax5, tx5 , tx8, wx5, wx6, wx7	82DHB	II	866.5750

Predicate Test Systems For The Measurement of Specific IgE

Pharmacia CAP System™ RAST FEIA	K894190, K911903
UniCAP™ Specific IgE Assay	K962274

Indications For Use Statement :

Allergen ImmunoCAP™ is the solid phase component of the Pharmacia & Upjohn *in vitro* immunodiagnostic systems which measure specific IgE to the respective allergen bound to the ImmunoCAP™. Allergen ImmunoCAP™ are intended to be used with Pharmacia CAP System™ RAST FEIA and UniCAP® Specific IgE *in vitro* diagnostic assays.

Pharmacia CAP System RAST® FEIA and UniCAP® Specific IgE are intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other findings, and are to be used in clinical laboratories, as well as, physician office laboratories.

General Description

Allergen ImmunoCAP™

Allergen ImmunoCAP™ consists of a cellulose sponge matrix to which allergenic components are covalently coupled. The matrix is encased in a small round plastic capsule. This capsule is at the same time a holder of the matrix for convenient automation and a reaction chamber.

The sponge matrix is manufactured from activated cellulose derivative to which allergen extract solution is added under defined optimized conditions for the allergen coupling. This solid phase is an excellent carrier of allergens and provides favorable reaction conditions.

UniCAP®/Pharmacia CAP System™ RAST FEIA Specific IgE Test Principle

The allergen of interest, covalently coupled to ImmunoCAP, reacts with the specific IgE in the patient serum specimen. After washing away non-specific IgE, enzyme labeled antibodies against IgE are added to form a complex. After incubation, unbound enzyme-anti-IgE is washed away and the bound complex is then incubated with a developing agent. After stopping the reaction, the fluorescence of the eluate is measured. The higher the response value, the more specific IgE is present in the specimen. To evaluate the test results, the response for the patient samples is compared directly to the response for the calibrators.

Performance Characteristics Of Allergen ImmunoCAP™

The safety and effectiveness of the test systems Pharmacia CAP System™ RAST FEIA and UniCAP™ Specific IgE for the determination of specific IgE antibodies have been established in previous 510(k) submissions. This 510(k) submission includes data to add 30 additional Allergen ImmunoCAP™ to the Pharmacia CAP System™ and UniCAP™ test systems for the measurement of specific IgE.

RAST inhibition verifies the immunological specificity of IgE binding for each allergen. The function of Allergen ImmunoCAP™ is further verified by testing clinical serum samples, with a history or indication of allergy to the specific allergen, and established negative samples. The analysis was performed in both Pharmacia CAP System™ and UniCAP ™ test systems and results show an outstanding agreement of outcome concerning positive and negative samples in both systems.

The importance of each allergen is demonstrated with relevant literature references covering frequency, clinical use and description of related allergens. Reproducibility between production lots and stability studies complete the picture by showing the constant quality of Allergen ImmunoCAP™.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 8 2000

Ms. Karen E. Matis
Manager, Regulatory Affairs and Quality Management
Pharmacia & Upjohn
Diagnostics Division, US Operation
7000 Portage Road
7425-248-01
Kalamazoo, Michigan 49001

Re: K000132
Trade Name: Allergen ImmunoCAP™ - c74, e89, ex2, ex70, ex71, ex73, fx8, fx9, fx10, fx16, fx73, i72, i75, i76, k71, k73, k81, k87, m80, m81, mx2, mx3, pax1, pax3, pax5, tx5, tx8, wx5, wx6, wx7
Regulatory Class: II
Product Code: DHB
Dated: January 17, 2000
Received: January 18, 2000

Dear Ms. Matis:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Allergen ImmunoCAP™ c74-wx7
510(k) Submission
Section 1. Indications For Use Statement

510(k) Number K000132

Device Name: **Allergen ImmunoCAP™**

Product No.	Code	Name
14-4854-01	c74	Gelatin
14-4356-01	e89	Turkey feathers
14-4324-01	ex2	Animal Epidermals & Protein Mix (e1, e5, e6, e87, e88)
14-4276-01	ex70	Animal Epidermals & Protein Mix (e6, e82, e84, e87, e88)
14-4277-01	ex71	Animal Epidermals & Protein Mix (e70, e85, e86, e89)
14-4828-01	ex73	Animal Epidermals & Protein Mix (e70, e85, e86, e213)
14-4845-01	fx8	Food Mix (f17, f18, f33, f49, f93)
14-4846-01	fx9	Food Mix (f20, f84, f87, f92, f259)
14-4847-01	fx10	Food Mix (f26, f27, f75, f83, f284)
14-4851-01	fx16	Food Mix (f44, f94, f208, f210)
14-4825-01	fx73	Food Mix (f26, f27, f83)
14-4361-01	i72	Green nimitti
14-4340-01	i75	European hornet
14-4362-01	i76	Berlin beetle
14-4364-01	k71	Castor bean
14-4400-01	k73	Silk waste
14-4365-01	k81	Ficus spp.
14-4370-01	k87	Alpha-amylase
14-4889-01	m80	Staphylococcal enterotoxin A
14-4890-01	m81	Staphylococcal enterotoxin B
14-4320-01	mx2	Mould/Yeast Mix (m1, m2, m3, m5, m6, m8)*
14-4891-01	mx3	Staphylococcal enterotoxins (m80, m81)
14-4350-01	pax1	Occupational Allergen Mix (e3, e4, e70, e85)
14-4352-01	pax3	Occupational Allergen Mix (m3, m6, g12, g15)
14-4354-01	pax5	Occupational Allergen Mix (k75, k76, k77, k79)
14-4201-01	tx5	Tree Pollen Mix (t2, t4, t8, t12, t14)*
14-4273-01	tx8	Tree Pollen Mix (t1, t3, t4, t7, t11)*
14-4197-01	wx5	Weed Pollen Mix (w1, w6, w7, w8, w12)*
14-4198-01	wx6	Weed Pollen Mix (w9, w10, w11, w18)*
14-4269-01	wx7	Weed Pollen Mix (w7, w8, w9,w10, w12)*

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Pharmacia CAP System RAST® FEIA and UniCAP® Specific IgE are intended for in vitro diagnostic use as an aid in the clinical diagnosis of IgE mediated allergic disorders in conjunction with other findings, and are to be used in clinical laboratories, as well as, physician office laboratories.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000132